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Balloon Angioplasty as the Primary Treatment for Failing Infra-inguinal Vein Grafts

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Abstract *Background:* We sought to evaluate the role of balloon angioplasty as the primary modality in the management of vein graft stenoses.
Methods: Patients who underwent infrainguinal vein graft bypass from January 2002 to December 2007 were enrolled into a surveillance program. Grafts which developed critical stenoses were identified and underwent urgent angiography with a view to angioplasty of the stenotic lesion. Lesions which were deemed unsuitable for angioplasty underwent urgent surgical repair.
Results: Four hundred and eleven grafts were followed up for a median of 19 months (range: 2—61). Ninety-six grafts (22.6%) developed critical stenosis. Twelve grafts occluded prior to repair and one was not intervened upon electively. Eight grafts underwent primary surgical repair. Seventy-six grafts underwent 99 endovascular procedures. Technical success was achieved in 60 grafts (78.9%). Of the grafts in which technical success had not been achieved, eight underwent repeat angioplasty and three were surgically repaired. Twenty-four grafts underwent repeat angioplasty for re-stenosis with a technical success rate of 71%. No difference was observed in graft patency ($P = 0.08$) or amputation rates ($P = 0.32$) between the grafts requiring intervention to maintain patency, and grafts which did not. Smoking [OR: 2.61 (95% CI: 1.51—4.53), ($P = 0.006$)], diabetes [OR: 2.55 (95% CI: 1.49—4.35), ($P = 0.006$)], renal failure [OR: 1.89 (95% CI: 1.19—3.38), ($P = 0.040$)] and recurrent stenosis [OR: 3.22 (95% CI: 1.63—4.69), ($P < 0.001$)] were risk factors for graft occlusion.
Conclusions: Balloon angioplasty of failing infrainguinal vein bypass grafts is safe and can be performed with an acceptable medium term patency rate, albeit with a significant risk of re-stenosis which can be successfully treated in most patients using repeat endovascular intervention.

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Introduction

Maintaining patency of infrainguinal vein bypass grafts has been a challenging task for vascular surgeons for decades.[1] These grafts are prone to the development of vein graft stenosis, which may precipitate failure of the bypass.[1–4]

Features associated with the development of vein graft stenosis are recognisable by duplex ultrasound scanning.[5] Duplex scanning has been widely used for graft surveillance, the rationale being that correction of stenotic lesions is likely to improve graft patency and reduce the risk of amputation.[6–13] Considerable uncertainty still exists about the optimal management of these threatened bypass grafts once they are identified. Traditional operative techniques such as patch angioplasty, interposition graft or replacement graft remain the gold standard for the management of vein graft stenosis. However these techniques require the availability of an additional autogenous vein and carry the risk of morbidity and mortality associated with re-operation. In addition, jump and interposition grafts used to treat vein graft stenosis may by themselves be at risk of development of vein graft stenosis.[13] Increased experience with the application of angioplasty in the treatment of stenoses in other venous conduits such as haemodialysis arterio-venous fistulae[14,15] has led to the introduction of this technique for the management of threatened bypass grafts.[16–20] However the efficacy of this treatment modality has been questioned[21] and to date no consensus exists about its primary use in the management of vein graft stenosis.

The aim of this study was to assess the efficacy and safety of balloon angioplasty as the primary modality in the management of vein graft stenoses, which are identified as a result of duplex vein graft surveillance.

Methods

Consecutive patients, who underwent infrainguinal bypass procedure using an autologous vein between 1st January 2002 and 31st December 2007 were studied. Infrainguinal vein bypass grafts were performed with a variety of techniques including reversed and in situ bypass grafts. The ipsilateral long saphenous vein was the conduit of choice for bypass. If this was found unsuitable the contralateral long saphenous vein was used. Short saphenous and arm veins were used in patients who had previous harvesting of the long saphenous vein or in whom the long saphenous vein had been found to be unusable.

Thereafter all patients were enrolled in a graft surveillance program. This involved duplex scanning and the measurement of ankle brachial index pressures before discharge from the hospital and at 6 weeks, 3 months, 6 months, 1 year and 2 years after operation. Duplex examination was performed by two experienced vascular technologists using an Acuson Sequoia duplex ultrasound system (Acuson, Redwood, California, USA) using a 5 MHz linear transducer. The duplex scanning protocol during vein graft surveillance included the assessment of inflow and outflow vessels for quality of flow based on velocity, waveforms and colour flow characteristics. Peak systolic velocity was measured at the sites of stenosis, at multiple sites within the graft and within the outflow vessel. The velocity ratio at the site of stenotic lesions was calculated. Any bypass grafts with sub critical flow abnormalities found on duplex scanning were studied more frequently at 3-month intervals, whilst all grafts with critical vein graft stenosis were referred for urgent angiography with a view to primary endovascular treatment. Table 1 shows the duplex parameters used to classify vein graft stenosis and indications for treatment.

Antegrade ipsilateral puncture was the preferred angiographic technique. Mixtures of standard and cutting balloon techniques were used. The size and the type of balloon (cutting versus standard balloon) used for angioplasty were based on the angiographic appearance and the site of the stenotic lesion within the vein graft. All interventions were evaluated with completion angiograms. Technical success was defined as a less than 20% stenosis remaining on completion angiogram (in keeping with the PTA guideline of the Society of Cardiovascular and Interventional Radiology).[22] Vascular laboratory evaluations, including duplex scans, ankle brachial indices, were obtained prior to discharge. Thereafter all patients re-entered the surveillance programme at the starting point. Patients with an unsuccessful endovascular procedure were admitted for urgent surgical correction of vein graft stenosis whilst those with residual stenosis were studied more frequently: at 2 weeks, 6 weeks and then, at 3-month intervals. This process was repeated for all patients who developed recurrent vein graft stenosis. Postoperative hypercholestrolemia was defined as the total cholesterol to high density lipoprotein cholesterol (total cholesterol/HDL) ratio of greater than 3.5. Renal failure was defined as the Kidney Dialysis Outcomes Quality Initiative (KDOQI) chronic kidney disease (CKD)[23] stage 4 or 5 at the time of infrainguinal bypass surgery.

Patient demographics, type of operation, conduit and follow up information were recorded in a computerized database (Microsoft™ Access® and Excel®, Redmond, Washington, USA). Data analysis was performed retrospectively. Results were analysed and reported in accordance with the reporting standards of the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery.[24] Statistical analysis was performed using *Statistical Package for Social Sciences* version 12 SPSS® (SPSS, Chicago, Illinois, USA) statistical software. Patency and limb salvage were determined using Kaplan–Meier analysis. The difference in primary assisted patency and amputation rates between patients who underwent angiography with a view to intervention for vein graft stenosis and patients who did not develop vein graft stenosis was assessed using the log rank test. $P < 0.05$ was considered significant.

Results

The initial patient group of 389 patients comprised 263 men (67.6%) and 126 women (32.4%) who underwent 411 bypass procedures. These grafts were followed up for a median of 19 months (range: 2–61). The median (range) age of the patients was 72 years (range: 38–87); 219 (56.3%) were current smokers, 168 (43.2%) had diabetes and 35 (9%) had

Table 1 The velocity criteria identifying different categories of vein graft stenosis identified through duplex surveillance (PSV: peak systolic velocity (cm/s), ABPI: ankle brachial pressure index)

	PSV at the site of stenosis		Post stenotic PSV	Drop in ABPI
	Absolute value	PSV ratio		
Critical stenosis (*urgent treatment*)	>300	3.5	<40	>0.15
Mild flow disturbance (*intensive surveillance*)	200–300	2	>45	<0.15
Low risk grafts (*standard surveillance*)	<200	<2	>45	<0.15

chronic renal failure. Three hundred and three patients (77.9%) were on statin therapy. Ninety-eight patients (25%) had hypercholestrolemia on follow up [median post-operative TC/HDL ratio: 3.1 (range: 0.8–4.3)]. The indications for surgery are shown in Table 2. Three hundred and fifty six bypasses were reversed vein grafts and 55 were in situ vein graft bypasses. Three hundred and fifty five bypasses (86.6%) had their origin at the femoral artery in the groin, 16 from the external iliac artery (3.9%) and 40 bypasses (9.7%) had their proximal anastomosis from the superficial femoral artery. The distal anastomoses were to the above knee popliteal (132, 34%), the below knee popliteal (148, 35%), and the tibial arteries (131, 31%).

During the follow up period, 272 grafts did not develop significant vein graft stenosis and therefore did not require intervention in order to maintain graft patency, whilst 96 grafts (22.6%) developed critical vein graft stenosis. A further 43 grafts (10.4%) occluded prior to the early post-operative (6 week) follow up scan The distribution of these stenoses along the length of the vein graft is shown in Fig. 1. Of these 12 grafts occluded prior to angiography and another graft occluded following diagnostic angiography, which revealed that the stenotic lesion identified, was not amenable to angioplasty. One graft was found to be stenotic for a significant proportion of its length and was electively not intervened upon. Eight grafts underwent open repair after diagnostic angiography, which identified lesions not amenable to angioplasty. This was due to inability to traverse the stenosis angiographically in three cases, an unfavourable proximal anastomotic lesion in two cases and external compression in a further three.

Seventy-six grafts underwent a total of 99 endovascular procedures (Figs. 2 and 3). Median age of the grafts at the time of the first angioplasty was 5 months (range: 7 weeks–27 months). Forty-one primary angioplasties were performed with a standard balloon and 34 with a cutting balloon. Initial technical success was achieved in 60 grafts (78.9%). Of the grafts in which initial technical success had not been achieved, eight underwent repeat angioplasty with good technical success and another graft was found to have thrombosed the next day. This graft was successfully managed with local catheter thrombolysis with good results. Three grafts occluded prior to attempted surgical repair and another four grafts were surgically repaired. A total of 27 grafts (45%) developed re-stenosis of which 24 underwent a repeat attempt at angioplasty, with technical success in 17 grafts (71%). Repeat angioplasties were performed with cutting balloons. Of the grafts that had developed re-stenosis three occluded prior to the repeat attempt at angioplasty and a further patient was deemed too unfit to undergo further intervention. There was no peri-procedural mortality. Vein graft angioplasty was associated with two puncture site haematomas both of which were treated conservatively; in addition one patient who had undergone cutting balloon angioplasty developed a delayed retroperitoneal hemorrhage from a contralateral puncture site which was managed by open surgery.

Table 2 Indication for infrainguinal vein graft bypass in the study population

Indication	Number	(%)
Intermittent claudication	39	9.5
Critical ischaemia	340	82.7
Popliteal artery aneurysm (asymptomatic)	18	4.4
Popliteal artery aneurysm (symptomatic)	14	3.4
Total	411	100

Follow up (months)	0	10	20	30	40
Grafts requiring no intervention	272	206	160	85	49
Grafts requiring intervention to maintain patency	96	75	49	33	18

Overall 30-month primary patency, primary assisted patency and secondary patency rates were 73.2%, 82.6% and 84.3%, respectively. No significant difference was observed in graft patency (log rank = 1.83, $P = 0.08$) or amputation rates (log rank = 0.89, $P = 0.32$) between the

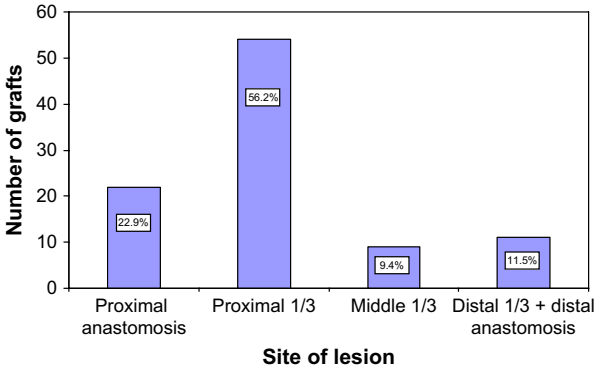


Figure 1 Distribution of duplex scan-detected stenoses identified during the surveillance program.

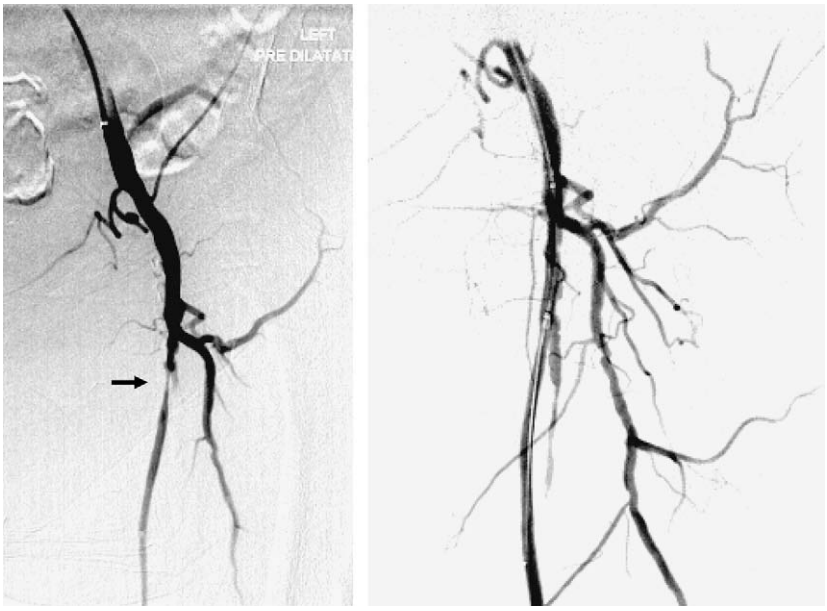


Figure 2 Digital subtraction angiograms of a common femoral to below knee popliteal artery bypass graft. The left image shows a proximal graft stenosis (arrowhead), whilst the right image shows the final result after cutting balloon PTA with a 4.0-mm diameter balloon.

grafts requiring intervention to maintain patency and grafts which did not (Figs. 4 and 5). Smoking [odds ratio: 2.61 (95% CI: 1.51—4.53), ($P = 0.006$)], diabetes [odds ratio: 2.55 (95% CI: 1.49—4.35), ($P = 0.006$)] and persistent hyperlipidemia [odds ratio: 1.89 (95% CI: 1.19—3.38), ($P = 0.04$)] were associated with reduced graft patency whilst the need for intervention in order to maintain graft patency was not [odds ratio: 1.41 (95% CI: 0.79—2.60), ($P = 0.180$)]. However recurrent graft stenosis was an independent risk factor for vein graft failure [odds ratio: 3.22 (95% CI: 1.63—4.69), ($P < 0.001$)] (Table 3). Similarly, continued smoking [odds ratio: 4.03 (95% CI: 2.07—7.84), ($P < 0.0001$)], diabetes [odds ratio: 2.86 (95% CI: 1.65—4.97), ($P = 0.0002$)] and persistent hyperlipidemia [odds ratio: 2.49 (95% CI: 1.39—4.47), ($P = 0.021$)] were associated with an increased risk of amputation, whereas the need for intervention in order to maintain graft patency was not [odds ratio: 1.24 (95% CI: 0.68—1.91), ($P = 0.32$)]. Recurrent vein graft stenosis was a risk factor for amputation of the ipsilateral limb [odds ratio: 2.51 (95% CI: 1.41—4.32), ($P = 0.002$)] (Table 4).

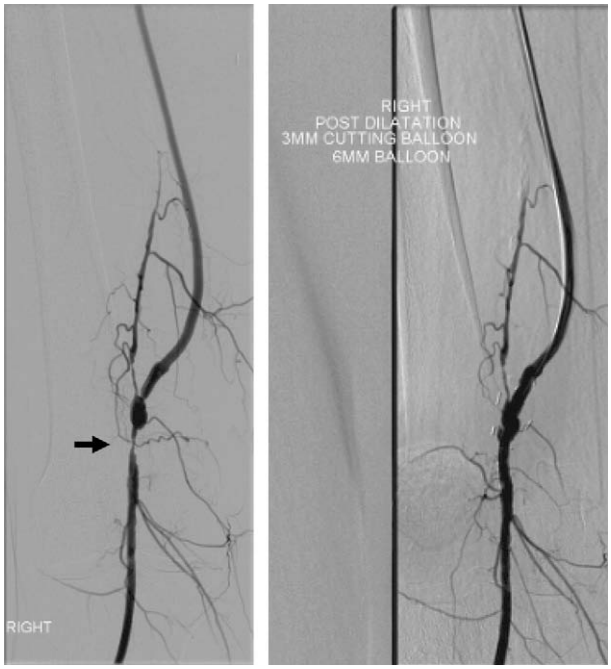


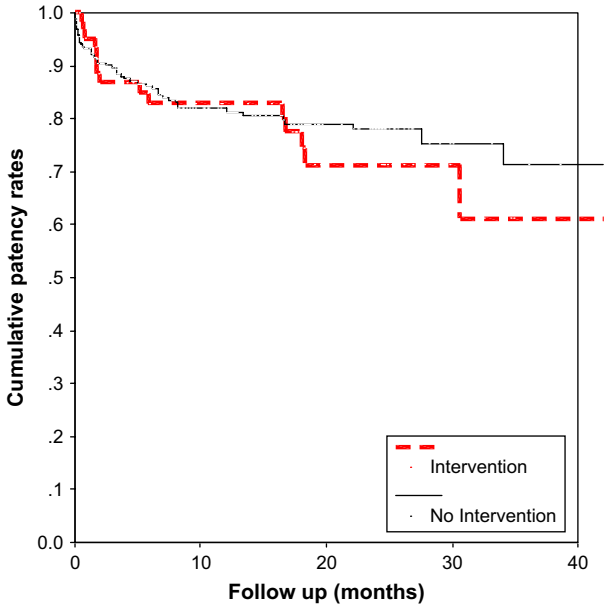
Figure 3 Digital subtraction angiograms of a common femoral to above knee popliteal artery bypass graft. The left image shows two distal anastomotic graft stenoses (arrowhead), whilst the right image shows the final result after cutting balloon PTA with a 3.0-mm diameter balloon.

Follow up (months)	0	10	20	30	40
Grafts requiring no intervention	272	206	160	85	49
Grafts requiring intervention to maintain patency	96	75	49	33	18

In addition vein graft surveillance identified two pseudoaneurysms associated with the proximal anastomosis, which were successfully treated with jump graft repair and three grafts with threatened inflow, which were treated with balloon angioplasty with successful technical results.

Discussion

The optimal treatment of a threatened vein graft bypass has been a source of debate for several decades. The controversy remains about the definition of a threatened



Follow up (months)	0	10	20	30	40
Grafts requiring no intervention	272	206	160	85	49
Grafts requiring intervention to maintain patency	96	75	49	33	18

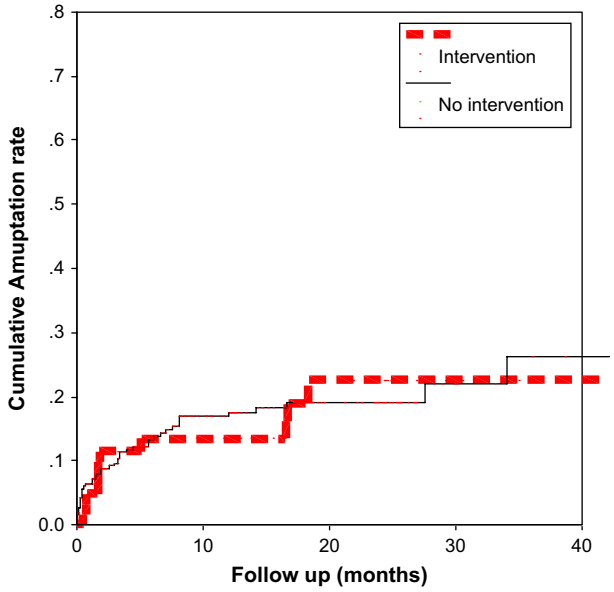
Figure 4 Kaplan–Meier plots of primary assisted patency over time in grafts which did not require intervention (black), compared with grafts which developed a significant stenotic lesion and underwent angiography with a view to endovascular intervention ($P = 0.08$).

infrainguinal vein bypass graft and also the clinical significance of the stenotic lesions once they are identified through duplex vein graft surveillance.[7] The authors offer graft surveillance to all patients who have undergone infrainguinal vein graft bypass procedures and this study relates to the efficacy of angioplasty for the management of these lesions rather than a discussion regarding the efficacy of duplex vein graft surveillance.

Surgical revision of failing infrainguinal vein grafts has been the gold standard in the management of vein graft stenosis. Techniques of vein patch angioplasty for short stenoses and interposition or jump graft repair for longer lesions have been associated with excellent medium[25] and long term patency rates.[26] Repair of critical vein graft stenosis has been shown to return patency and amputation rates of the affected vein grafts to levels approaching that of vein grafts with no significant stenosis.[13] On the other hand surgical repair of vein graft stenosis is an invasive procedure requiring general or regional anaesthesia in a population of patients with significant co-morbidity. It is also partly dependent on the availability of an appropriate length of an additional venous conduit. In addition revised vein grafts are themselves at risk of development of vein graft stenosis.[13,26–28] Therefore percutaneous transluminal angioplasty, if successful, is an attractive option for the management of vein graft stenosis.

Some years ago Berkowitz *et al*. reported on the results of selective use of angioplasty for the management of vein graft stenosis. They performed angioplasty as the primary treatment modality in 81% of failing infrainguinal reversed vein grafts.[28] The rest were repaired by short jump grafts. They reported a 5-year primary assisted patency rate of 61%. Lesions in the proximal graft, proximal anastomosis, and distal graft taken as a group had significantly better patency than the mid-graft and distal anastomotic lesions.[28] Subsequent authors have reported similar results following vein graft angioplasty.[29–32] Alexander *et al*. reported a significantly lower primary assisted patency after percutaneous transluminal angioplasty (PTA) for the treatment of vein graft stenosis, with failure rates of 31% at 6 months, 55% at 1 year, and 63% at 2 years.[21] The main reason for failure of PTA in their series was the development of recurrent vein graft stenosis.

In this study a significant proportion of grafts, which had undergone angioplasty with a satisfactory technical result, developed re-stenosis, requiring secondary procedures. In the majority of patients the secondary procedure was endovascular with a technical success rate approaching that of angioplasty for primary vein graft stenosis. Carlson *et al*. reported their experience of PTA of infrainguinal vein graft stenoses in 36 patients. Their initial technical success rate was 91% and overall graft patency rate was 78% at 24 months.[31] However, nine bypasses (25%) required further attempts at angioplasty for recurrent vein graft stenosis and seven grafts required secondary procedures.[31] This high-lights the importance of continued graft surveillance and maintenance intervention in patients in whom successful endovascular repair of vein graft stenosis has been achieved. After successful treatment of vein graft stenosis our practice was to re-enter the graft at the starting point of vein graft surveillance. This resulted in most re-stenoses being identified and treated in a timely manner.



Follow up (months)	0	10	20	30	40
Grafts requiring no intervention	272	206	160	85	49
Grafts requiring intervention to maintain patency	96	75	49	33	18

Figure 5 Kaplan–Meier plots of amputation rates over time in grafts which did not require intervention (black), compared with grafts which developed a significant stenotic lesion and underwent angiography with a view to endovascular intervention ($P = 0.32$).

A number of authors have reported that, notwithstanding the higher re-stenosis rates and the need for re-intervention, the results of endovascular treatment for vein graft stenosis are equivalent to open surgical repair.[18,32,33] Although most of these observations were performed in small studies with heterogenous patient groups which were not randomized, they were potentially subject to type II error. Avino *et al*. reviewed a series of 144 infrainguinal vein graft stenoses from a population of 528 grafts, which were under surveillance over a period of 6 years.[26] Seventy-seven of the failing grafts were treated with open surgical repair and 67 were treated using PTA. They reported similar stenosis free patency rates of 63% for both groups[26] and no significant difference in patency rates between interventions for primary versus recurrent vein graft stenoses or between infra-genicular and supra-genicular bypasses.[26] However this has not been a universal observation; Berceli *et al*. reported that open surgical revascularization imparts an improved graft survival over endovascular interventions. They also observed no significant difference in the hospital length of stay or global quality of life between the two groups.[34] One might postulate these outcomes would be potential benefits of endovascular intervention.[34] In this study renal failure was a risk factor for vein graft failure.

The use of cutting balloon angioplasty is a relatively new development for the management of vein graft stenosis.

Table 3 Factors affecting primary assisted patency after infrainguinal bypass assessed using Cox's multivariate regression analysis

Variable	Hazard ratio (95% CI)	Significance (*P*)
Age	1.03 (0.62–1.36)	0.85
Gender	0.98 (0.71–1.10)	0.61
Diabetes	2.55 (1.49–4.35)	0.006
Smoking	2.6133 (1.51–4.53)	0.006
Renal failure	0.80 (0.36–1.80)	0.592
Hyperlipidemia	1.89 (1.19–3.38)	0.040
Intervention to maintain graft patency	1.41 (0.79–2.60)	0.18
Recurrent stenosis	3.22 (1.63–4.69)	<0.001

Table 4 Factors affecting amputation rates after infrainguinal bypass assessed using Cox's multivariate regression analysis

Variable	Hazard ratio (95% CI)	Significance (*P*)
Age	1.12 (0.41–1.53)	0.41
Gender	0.86 (0.51–1.21)	0.52
Diabetes	2.8618 (1.65–4.97)	0.002
Smoking	4.03 (2.07–7.84)	<0.001
Renal failure	0.93 (0.42–2.057)	0.852
Hyperlipidemia	2.49 (1.39–4.47)	0.021
Intervention to maintain graft patency	1.24 (0.68–1.91)	0.310
Recurrent stenosis	2.51 (1.41–4.32)	0.002

Engelke *et al*. reviewed their preliminary experience in the use of cutting balloon PTA for the treatment of infrainguinal vein graft stenosis.[20] They reported 18-month primary assisted and secondary patency rates of 67% and 83% respectively. A larger study by Garvin *et al*. appears to confirm that cutting balloon angioplasty is associated with a high technical success rate but they reported relatively low term patency and higher complication rates. They therefore cautioned against its widespread use for the treatment of vein graft stenosis.[35]

In this study in 16 grafts (20.6%) at the time of initial attempt at angioplasty satisfactory technical success was not achieved. These grafts are at a significant risk of early graft occlusion. Therefore consideration should be given to immediate or early surgical or endovascular re-intervention. Our practice was to perform duplex reassessment of the stenotic lesion following the angioplasty attempt. Grafts, which had a persistent severe stenosis, underwent urgent surgical repair. Whilst grafts with intermediate residual stenosis underwent early duplex follow up with a repeat attempt at angioplasty if clinically indicated. Experience with other arterialized venous conduits suggests that immediate attempts at repeat angioplasty of venous conduits with cutting balloons are associated with a risk of graft rupture.[36–38]

Multivariate analysis offers some interesting insight into the factors that may influence outcomes after endovascular intervention. Not unexpectedly, smoking and diabetes were significant risk factors for graft occlusion and amputation. In addition hypercholestrolemia during follow up was associated with increased risk of graft occlusion and amputation. The authors used this as a surrogate marker of compliance with statin therapy. Berceli *et al*. reported that statin therapy was associated with improved graft durability after both endovascular and surgical revision. In addition they found that the diagnosis of hypertension was also associated with improved primary assisted patency following open and endovascular intervention for vein graft stenosis. They postulated that the reason for the latter observation may have been related to the treatment the patients were receiving for hypertension such as angiotensin converting enzyme (ACE) inhibitors or calcium channel blockers.[34] Chronic renal failure is a recognised risk factor for vein graft failure; a recent publication by Arvela *et al*. reports that the estimated glomerular filtration rate predicts the predictor of survival, leg salvage and amputation free survival in patients with critical lower limb ischaemia.[39]

Critical vein graft stenosis is a complex clinical problem. Provided that grafts are surveyed closely, primary endovascular treatment of failing infrainguinal vein grafts appears to be safe and is associated with acceptable early and medium term patency rates.

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Conflict of Interest

None declared.

Ethical Approval

N/A.

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